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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,701	06/27/2003	Mark V. Vandewalle	5490-000283	9681
27572	7590	03/20/2006	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			ARAJ, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,701

Applicant(s)

VANDEWALLE, MARK V.

Examiner

Michael J. Araj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13-15 and 17-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13-15 and 17-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final rejection mailed January 27, 2006 has been withdrawn due to further investigation.

Status of Claims

Claims 1,3-11,13-15,17-30 and 31-41 are pending.

Claim Objections

Claims 1 and 19 are objected to for the following informalities:

Claim 1 and 19 are objected to for the following reason. There exists an inconsistency between the language of claim 1 and 19, thus making the scope of the claim unclear. In the preamble of claim 1, line 1, applicant recites "A bone screw anchor system" directing it to the combination. However, in claim 1, lines 11 and 12, applicant mentions "the implant" and "the fastening device" as part of the invention, i.e. "comprising of a bone screw anchor, bone plate, and fastening device", thus indicating that the combination, the bone screw anchor, the implant and the fastening device, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination.

Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 1 and 19 will be considered as being drawn to the subcombination, bone screw anchor

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-11,13-15, 17-24 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultheiss et al. (U.S. Patent No. 6,755,835) in view of Wolf (U.S. Patent No. 6,629,977).

Schultheiss et al. discloses a bone screw anchor (10) that is operable to secure an implant to a bone that has and externally threaded (14) intermediary portion; a pointed self-tapping tip, comprising of a cutting flute that extends across a part of the intermediary portion, located at a first end of said intermediary portion; a collared head, comprising of a cutting flute, located at a second end opposite of said tip that has an interface capable with a driving tool; and a threaded interior (55) bore (50) extending through said head and through said intermediary portion, where it is operable with threads of the fastening device (a screw) to secure the implant to the bone (see Fig. 1 below). Schultheiss et al. also discloses a port (62) on the sides of the anchor that can communicate with the interior bore (50) that is at least partially filled with bone cement, an intermediary portion that is completely threaded that has a larger diameter than the tip and an interface of said head that has at least one recess (54) operable to mate with said driver.

Schultheiss et al. discloses the method steps of securing an implant to a bone which includes implanting a bone screw anchor within the bone using a driving tool operable with the head of the anchor; injecting bone cement into a threaded bore extending through the head to at least a portion of the intermediary portion using a cement delivery device that allows the anchor to be secured; and securing the implant to the anchor using a threaded fastening device secure within the bore. Schultheiss et al. also discloses that the internally threaded portion is inherently protected during the ejecting step, the delivery device is connected to the internal thread of the anchor to protect the threads from being contaminated with bone cement during the injecting step and the bone cement exits at least one port located on the side of the anchor.

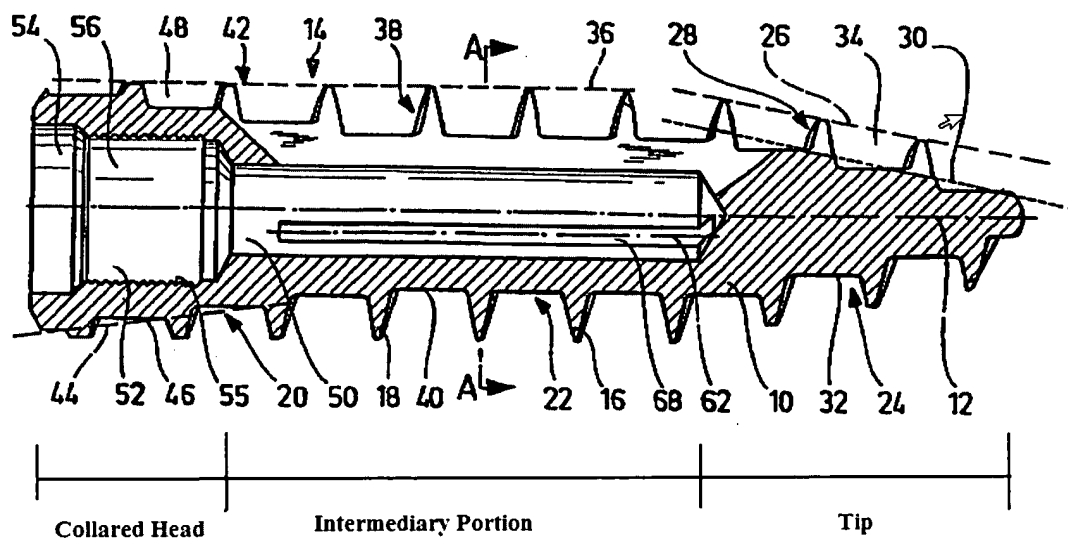


Figure 1

Schultheiss discloses the claimed invention except for and open tip or a screw head having grooves. Wolf discloses a groove to receive a driving tool to optimize

torque capacity when inserting the device. Wolf also discloses an open tip (30) so that a guide pin may be used during delivery and installation. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Schultheiss with a head defining a groove as well as an open tip in view of wolf, in order to have a device that can be installed with ease and accuracy.

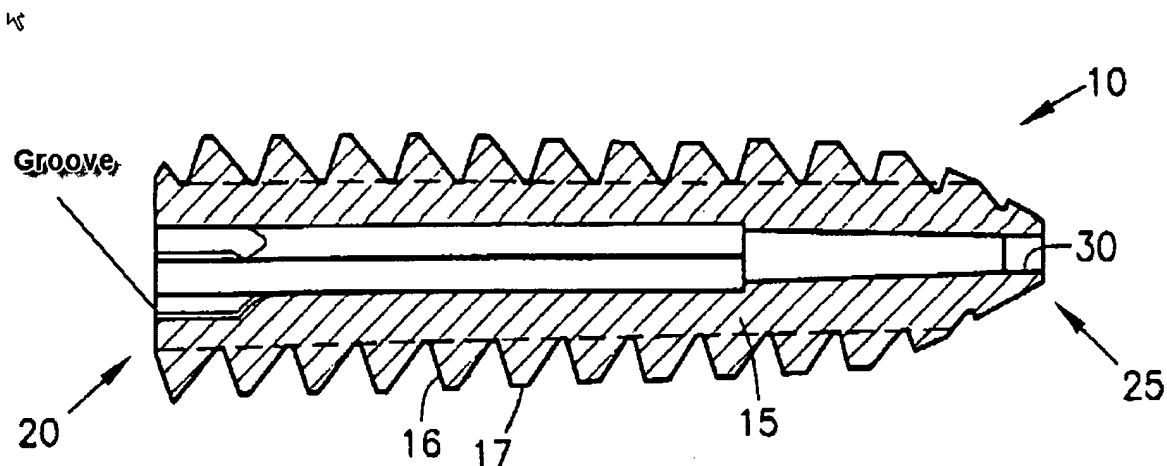


Figure 2

Claims 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultheiss et al. (U.S. Patent No. 6,755,835) in view of Wolf (U.S. Patent No. 6,629,977), as applied to claim 1 above, and further in view of Tronzo (U.S. Patent No. 4,653,489).

The combination of Schultheiss et al. and Wolf, as applied to claim 1, discloses the claimed invention except for the combination of the delivery system comprising a bone cement receptacle and a threaded tube connected to said receptacle as well as the anchor being comprised of a resorbable material. Tronzo discloses a delivery apparatus (50) comprising of a bone cement receptacle and a threaded tube connected

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to it that is operable with the threads of the bore. The delivery apparatus (50) further comprises of a stem (46) that extends from the threaded tube, where the stem (46) terminates in a disk in order to have an easier installation process of the device (Col. 3, Paragraph 7). With regard to the screw anchor being made of resorbable material, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make this anchor out of resorbable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultheiss et al. (U.S. Patent No. 6,755,835) in view of Baker et al. (U.S. Patent No. 5,569,251).

Schultheiss et al. disclose the claimed invention except for placing an implant over the anchor and fastening the implant to the anchor using a fastening device. Barker et al. disclose the method of placing the implant, in this case a bone plate, over the anchors and using a fastening device to the anchor in order to secure the assembly and strengthen the bone. It would have been obvious to one skilled in the art at the time the invention was made to have the method of securement of schultheiss and applying it with a bone plate in view of baker et al., in order to have secure support for a damaged bone and allow it to heal accordingly.

Response to Arguments

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

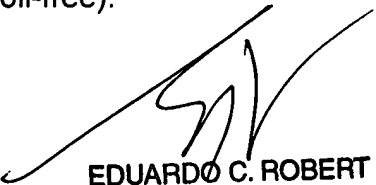
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJA


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER